



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, Maryland 20892-6910
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

December 14, 2021

Re: Animal Welfare Assurance
A3034-01 [OLAW Case Z]

Dr. Michael R. Kuhlman
Institutional Official
Battelle Memorial Institute - Columbus
550 King Avenue
Columbus, OH 43201

Dear Dr. Kuhlman,

Dear Dr. Kuhlman,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 16, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Battelle Memorial Institute - Columbus following up on an initial October 4, 2021 notification by email.

According to the information provided, this Office understands that the Batelle Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: failure to adhere to the IACUC-approved protocol. The final report states a mouse was not euthanized when the animal reached the protocol-specific endpoint. It is also stated the animal technician involved in the incident was interviewed and additional staff were counseled to monitor their work closely. The IACUC was notified of the matter and accepted the corrective action plan. The corrective action plan included the following:

- Data captured on paper has resumed. This method has been successfully used on multiple studies previously without this type of incident occurring.
- Any weight measuring less than the threshold weight (minimum allowable weight as defined by the protocol) identifies those animals that have met the endpoint and thereby initiates euthanasia of that animal.
- Staff may export data captured in the software system to an Excel spreadsheet set with conditional formatting to flag when an animal has met the protocol-specific weight loss criteria.

It is noted that this research is supported by funding from HHS and understood the funding component has been notified of the event as well. Based on its assessment of this explanation, OLAW understands that the Battelle Memorial Institute - Columbus has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy.

We appreciate being informed of these matters and find no cause for further action by this Office.

Page 2 - Dr. Kuhlman
December 14, 2021
OLAW Case A3034-Z

Sincerely,

Jacquelyn

T. Tubbs -S

Jacquelyn Tubbs, DVM, DACLAM
Senior Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

Digitally signed by
Jacquelyn T. Tubbs -S
Date: 2021.12.14
11:15:58 -05'00'

cc: IACUC Contact

(b) (6)

November 16, 2021

Axel Wolff, MS, DVM
Deputy Director
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892

Dear Dr. Wolff:

Battelle, in accordance with Assurance D16-00021 (A3034-01) and PHS Policy, provides this report of noncompliance regarding an adverse event. This incident was first reported on September 28, 2021 via email to OLAW's Division of Compliance Oversight. This document is our final report relative to this incident which we identified as noncompliant with PHS Policy.

One mouse on an IACUC-approved protocol was not euthanized when it reached the protocol-specified endpoint (failure to adhere to the IACUC-approved protocol). The following corrective and preventive actions were implemented after the incident:

- On September 22, 2021, the involved animal technician was interviewed, and on September 23, 2021, additional staff members were counselled to check their work closely.
- The data collection system was reviewed relative to the preset "flags" intended to prompt the animal technician if euthanasia criteria were met.
- The IACUC was notified of this occurrence on September 23, 2021. The IACUC reviewed and accepted the corrective action plan as described below. A meeting was held September 22, 2021, with management and IACUC leadership, and on September 24, 2021, a follow up meeting including the study directors occurred.

Data capture on paper has resumed. This method of data capture has successfully been used previously on numerous studies without this type of incident occurring. This paper record contains columns for animal ID, initial weight, threshold weight, and whether threshold was reached or exceeded. Threshold weight is the minimum allowable weight as defined by protocol. Any weight measuring less than that threshold easily identifies those animals that have met endpoint and thereby initiate euthanasia of that animal. Discussions about adding and/or modifying additional parameters have occurred with the software company and modifications or additions are not possible. Additionally, staff can export data captured in the software system to an Excel spreadsheet set with conditional formatting to flag when an animal has met the protocol-specified weight loss criteria.

The contract number is HHSN273201700005C. There were no unallowable costs charged. This incident was reported to the funding component.

Should you have any questions regarding this report, please let me know.

Thank you.

(b) (6)

Michael R. Kuhlman, Ph.D.
Institutional Official
Battelle

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(c) kuhlmanm@battelle.org

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, November 26, 2021 7:15 AM
To: Kuhlman, Michael (US)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: B06215 Final Report

Thank you for this report, Dr. Kuhlman. We will send a response soon.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: (b) (6) On Behalf Of Kuhlman, Michael (US)
Sent: Monday, November 22, 2021 11:05 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Kuhlman, Michael (US) <KUHLMANM@battelle.org>
Subject: B06215 Final Report

Dear OLAW,

Attached is the B06215 final report from Battelle. Please feel free to contact us with any questions.

V/r,

Michael R. Kuhlman, Ph.D.

Chief Scientist

(b) (6)

kuhlmanm@battelle.org

Battelle

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Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, October 6, 2021 6:54 AM
To: Kuhlman, Michael (US)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Reportable incident

Thank you for this preliminary report, Dr. Kuhlman. We will start a new case file.

Axel Wolff, M.S., D.V.M.
 Deputy Director, OLAW

-----Original Message-----

From: Kuhlman, Michael (US) <KUHLMANM@battelle.org>
Sent: Monday, October 4, 2021 9:06 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Reportable incident

Dear Division of Compliance Oversight:

A situation recently occurred at Battelle which we deemed reportable. We instituted immediate corrective actions, the details of which are provided below.

Animal Welfare Assurance number: D16-00021 (A3034-01)

Funding component and if contacted: NTP; notification pending.

Description of the incident:

One mouse on an IACUC-approved protocol was not euthanized when the protocol-specified endpoint was reached. That mouse was found to have died during the next inspection.

Description of actions taken:

- * The animal technician was interviewed.
- * The data collection system was reviewed relative to the preset "flags" intended to prompt the animal technician if euthanasia criteria were met.
- * It was determined the data collection system is unable to be modified to better capture protocol-specific data endpoints that would be useful in alerting staff to these animals. Discussions about adding and/or modifying additional parameters have occurred with the software company and modifications or additions are not possible.
- * The IACUC was notified on September 23, 2021.

Corrective plans included:

- * Data capture on paper has resumed. This method of data capture has successfully been used previously on numerous studies without this type of incident occurring. This paper record contains columns for animal ID, initial weight, threshold weight, and whether threshold was reached or exceeded. Threshold weight is the minimum allowable weight as defined by protocol. Any weight measuring less than that threshold easily identifies those animals who have met endpoint and thereby initiate euthanasia of that animal.

* Additionally, staff are performing a test run on exporting data captured in Provantis to an Excel spreadsheet set with conditional formatting to alarm when an animal has met the protocol-specified weight loss criteria. This process has been used previously on unrelated studies.

* A meeting was held September 22, 2021 with management and IACUC leadership, and on September 24, 2021, a follow up meeting including the study directors occurred.

* Staff members were counselled to check their work closely.

A signed copy of the final report will be provided no later than October 12, 2021.

Please contact me if you require additional information.

V/r

Michael R. Kuhlman, Ph.D.

Institutional Official

(b) (6)

kuhlmanm@battelle.org<mailto:kuhlmanm@battelle.org>

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